

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Kukolj, George et al) Art Unit: To be assigned
U.S. Appln. No. : To be assigned) Examiner: To be assigned
Confirmation No. : To be assigned
U.S. Filing Date : February 27, 2004
Title of Invention : SELF-REPLICATING RNA MOLECULE FROM HEPATITIS C
VIRUS
Attny. Docket No.: 13/083-3-D2

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

February 27, 2004

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§ 1.56 and 1.97, as more specifically described herein below. Copies of cited references can be found in prior application number 10/309,561, filed on December 4, 2002.

1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

- A statement as specified in 37 C.F.R. §1.97(e) [see below]; or
- The fee set forth in 37 C.F.R. §1.17(p).

The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

1.97(e).

Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

The fee set forth in 37 C.F.R. §1.17(p).

The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,

Susan K. Pocchiari

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Certificate of Mailing

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as Express mail EV 376716394 US in an envelope addressed to:

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on February 27, 2004.

Susan K. Pocchiari

Susan K. Pocchiari, Reg. No. 45,016

<p>Substitute for form 1449A/PTO</p> <p>PATENT DOCUMENTS SUBMITTED BY APPLICANT</p>				Complete If Known	
				Application Number	To be assigned
				Filing Date	February 27 2004
				First Named Inventor	Kukolj, George
				Group Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	1	of	5	Attorney Docket Number	13/083-3-D2

U.S. PATENT DOCUMENTS						
Examiner Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
AUS1		20020142350		Kukolj, George	10-3-2002	
AUS2		20030148348		Kukolj, George	08-07-2003	
AUS3						
AUS4						
AUS5						
AUS6						
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FOREIGN PATENT DOCUMENTS								
Examiner Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office	Number	Kind Code (if known)				
AF1			WO 98/04008		Motorola Inc.	29-01-1998		<input type="checkbox"/>
AF2			WO 98/39031		Washington University	11-09-1998		<input type="checkbox"/>
AF3			WO 00/66623		Boehringer Ingelheim (Canada) Ltd.	09-11-2000		<input type="checkbox"/>
AF4			WO 01/89364 A2		Washington University	29-11-2001		<input type="checkbox"/>
AF5								<input type="checkbox"/>
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AF8								<input type="checkbox"/>
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AF10								<input type="checkbox"/>

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<p>Substitute for form 1449B/PTO</p> <p>NON-PATENT DOCUMENTS SUBMITTED BY APPLICANT</p>			Complete If Known	
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
	AO1	FOURNIER, SUREAU et al.; In vitro infection of adult normal human hepatocytes in primary culture by hepatitis C virus; J. Virol.; 1998, V. 79; 2367-2374	<input type="checkbox"/>
	AO2	GRAKOUI, WYCHOWSKI et al.; Expression and Identification of Hepatitis C Virus Polyprotein Cleavage Products; J. Virol.; 1993, V. 67, No. 3; 1385-1395	<input type="checkbox"/>
	AO3	HIJIKATA, MIZUSHIMA et al.; Two Distinct Proteinase Activities Required for the Processing of a Putative Nonstructural Precursor Protein of Hepatitis C Virus; J. Virol.; 1993, V. 67, No. 8; 4665-4675	<input type="checkbox"/>
	AO4	BARTENSCHLAGER, AHLBORN-LAAKE et al.; Nonstructural Protein 3 of the Hepatitis C Virus Encodes a Serine-Type Proteinase Required for Cleavage at the NS3/4 and NS4/5 Junctions; J. Virol.; 1993, V. 67, No. 7; 3835-3844	<input type="checkbox"/>
	AO5	REED, XU et al.; Phosphorylation of the Hepatitis C Virus NS5A Protein In Vitro and In Vivo: Properties of the NS5A-Associated Kinase; J. Virol.; 1997, V. 71, No. 10; 7187-7197	<input type="checkbox"/>
	AO6	KHROMYKH, WESTAWAY; Subgenomic Replicons of the Flavivirus Kunjin: Construction and Applications; J. Virol.; 1997, V. 71, No. 2; 1497-1505	<input type="checkbox"/>
	AO7	BEHRENS, GRASSMANN et al.; Characterization of an Autonomous Subgenomic Pestivirus RNA Replicon; J. Virol.; 1998, V. 72, No. 3; 2364-2372	<input type="checkbox"/>
	AO8	MIZUTANI, KATO et al.; Characterization of Hepatitis C Virus Replication in Cloned Cells Obtained from a Human T-Cell Leukemia Virus Type 1-Infected Cell Line, MT-2; J. Virol.; 1996, V. 70, No. 10; 7219-7223	<input type="checkbox"/>
	AO9	MOSER, TRATSCHIN et al.; A Recombinant Classical Swine Fever Virus Stably Expresses a Marker Gene; J. Virol.; 1998, V. 72, No. 6; 5318-5322	<input type="checkbox"/>
	AO10	IKEDA, SUGIYAMA et al.; Human hepatocyte clonal cell lines that support persistent replication of hepatitis C virus; Virus Research; 1998, V. 56; 157-167	<input type="checkbox"/>
	AO11	DASH, HALIM et al.; Transfection of HepG2 Cells with Infectious Hepatitis C Virus Genome; Amer. J. Pathology; 1997, V. 151; 363-373	<input type="checkbox"/>

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Substitute for form 1449B/PTO NON-PATENT DOCUMENTS SUBMITTED BY APPLICANT				Complete If Known	
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	AO1	KIM, MORGENSTERN et al.; Hepatitis C virus NS3 RNA helicase domain with a bound oligonucleotide: the crystal structure provides insights into the mode of unwinding; <i>Structure</i> ; 1998, V. 6; 89-100	<input type="checkbox"/>
	AO2	YAN, LI et al.; Complex of NS3 protease and NS4A peptide of BK strain hepatitis C virus; A 2.2 Å resolution structure in a hexagonal crystal form; <i>Protein Science</i> ; 1998, V. 7; 837-847	<input type="checkbox"/>
	AO3	YAO, HESSON et al.; Structure of the hepatitis C virus RNA helicase domain; <i>Nature Structural Biology</i> ; 1997, V. 4, No. 6; 463-467	<input type="checkbox"/>
	AO4	ITO, MUKAIGAWA et al.; Cultivation of hepatitis C virus in primary hepatocyte culture from patients with chronic hepatitis C results in release of high titre infectious virus; <i>J. Gen. Virol.</i> ; 1996, V. 77; 1043-1054	<input type="checkbox"/>
	AO5	YOO, SELBY et al.; Transfection of a Differentiated Human Hepatoma Cell Line (Huh7) with In Vitro-Transcribed Hepatitis C Virus (HCV) RNA and Establishment of a Long-Term Culture Persistently Infected with HCV; <i>J. Virol.</i> ; 1992, V. 69, No. 1; 32-38	<input type="checkbox"/>
	AO6	AGO, ADACHI et al.; Crystal structure of the RNA-dependent RNA polymerase of hepatitis C virus; <i>Structure</i> ; 1999, V. 7; 1417-1426	<input type="checkbox"/>
	AO7	BLIGHT, KOLYKHALOV et al.; Efficient Initiation of HCV RNA Replication in Cell Culture; <i>Science</i> ; 2000, V. 290; 1972-1974	<input type="checkbox"/>
	AO8	BRESSANELLI, TOMEI et al.; Crystal structure of the RNA-dependent RNA polymerase of hepatitis C virus; <i>PNAS</i> ; 1999, V. 96, No. 23; 13034-13039	<input type="checkbox"/>
	AO9	CHO, HA et al.; Crystal Structure of RNA Helicase from Genotype 1b Hepatitis C Virus; <i>J. Biol. Chemistry</i> ; 1998, V. 273, No. 24; 15054-15052	<input type="checkbox"/>
	AO10	GALE JR., KORTH et al.; Evidence that Hepatitis C Virus Resistance to Interferon is Mediated through Repression of the PKR Protein Kinase by the Nonstructural 5A Protein; <i>Virology</i> ; 1997, V. 230; 217-227	<input type="checkbox"/>
	AO11	GRAKoui, MCCOURT et al.; A second hepatitis C virus-encoded proteinase; <i>Proc. Natl. Acad. Sci. USA</i> ; 1993, V. 90; 10583-10587	<input type="checkbox"/>

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<p>Substitute for form 1449B/PTO</p> <p>NON-PATENT DOCUMENTS SUBMITTED BY APPLICANT</p>				Complete If Known	
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	AO1	KWONG, KIM et al.; Hepatitis C virus NS3/4A protease; Antiviral Research; 1998, V. 40; 1-18	<input type="checkbox"/>
	AO2	LANFORD, SUREAU et al.; Demonstration of in Vitro Infection of Chimpanzee Hepatocytes with hepatitis C Virus Using Strand-Specific RT/PCR; Virology; 1994, V. 202; 606-614	<input type="checkbox"/>
	AO3	LESBURG, CABLE et al.; Crystal structure of the RNA-dependent RNA polymerase from hepatitis C virus reveals a fully encircled active site; Nat. Struc. Biolo.; 1999, V. 6, No. 10; 937-943	<input type="checkbox"/>
	AO4	LOHMANN, KORNER et al.; Replication of Subgenomic Hepatitis C Virus RNAs in a Hepatoma Cell Line; Science; 1999, V. 285; 110-113	<input type="checkbox"/>
	AO5	LOHMANN, KORNER et al.; Mutations in Hepatitis C Virus RNAs Conferring Cell Culture Adaptation; J. Virology; 2001, V. 75, No. 3; 1437-1449	<input type="checkbox"/>
	AO6	LOVE, PARGE et al.; The Crystal Structure of Hepatitis C Virus NS3 Proteinase Reveals a Trypsin-like Fold and a Structural Zinc Binding Site; Cell; 1996, V. 87, 331-342	<input type="checkbox"/>
	AO7	SHIMIZU, PURCELL et al.; Correlation between the infectivity of hepatitis C virus <i>in vivo</i> and its infectivity <i>in vitro</i> ; Proc. Natl. Acad. Sci. USA; 1993, V. 90, 6037-6041	<input type="checkbox"/>
	AO8	YANAGI, ST. CLAIRE et al.; In <i>vivo</i> analysis of the 3' untranslated region of the hepatitis C virus after <i>in vitro</i> mutagenesis of an infectious cDNA clone; Proc. Natl. Acad. Sci. USA; 1999, V. 96, 2291-2295	<input type="checkbox"/>
	AO9		<input type="checkbox"/>
	AO10		<input type="checkbox"/>
	AO11		<input type="checkbox"/>

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	AO1	GOU, JU-TAO et al.; Effect of Alpha Interferon on the Hepatitis C virus Replicon; J. Virol.; 2001, 75(18):8516-8523			<input type="checkbox"/>
	AO2	HIJIKATA, MAKOTO et al.; Gene mapping of the putative structural region of the hepatitis C virus genome by in vitro processing analysis; Proc. Natl. Acad. Sci.; 1991, 88:5547-5551			<input type="checkbox"/>
	AO3	KIM, DONG WOOK et al.; C-Terminal Domain of the Hepatitis C Virus NS3 Protein Contains an RNA Helicase Activity; 1995, 215(1):160-166			<input type="checkbox"/>
	AO4	KIM, J.-E. et al; Subcellular localization of hepatitis C viral proteins in mammalian cells; Arch Virol.; 1999, 144:329-343			<input type="checkbox"/>
	AO5	KIM, J.L. et al; Crystal Structure of the Hepatitis C Virus NS3 Protease Domain Complexed with a Synthetic NS4A Cofactor Peptide; Cell; 1996, 87:343-355			<input type="checkbox"/>
	AO6	KRIEGER, NICOLE, et al; Enhancement of Hepatitis C Virus RNA Replication by Cell Culture-Adaptive Mutations; J. of Virol.; 2001, 75(10):4614-4624			<input type="checkbox"/>
	AO7				<input type="checkbox"/>
	AO8				<input type="checkbox"/>
	AO9				<input type="checkbox"/>
	AO10				<input type="checkbox"/>
	AO11				<input type="checkbox"/>

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